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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/228,866	01/12/99	RUOSLAHTI E	P-LJ3430

EXAMINER	
TURNER,S	
ART UNIT	**PAPER NUMBER**
1644	9

HM12/0216

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DATE MAILED: 02/16/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/228,866	Ruoslahti E
Examiner	**Group Art Unit**
Sharon L. Turn r, Ph.D.	1644

☒ Responsive to communication(s) filed on *5-14-99*

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *13-41* is/are pending in the applicat

Of the above, claim(s) *13, 21-23, and 25-27* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *14-20, 24, and 28-41* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *13-41* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Response to Amendment

1. The Art Unit of U.S. Patent application SN 09/228,866 has changed. In order to expedite the correlation of papers with the application please direct all future correspondence to Examiner Turner, Technology Center 1600, Art Unit 1644.

2. The amendment filed 11-29-99 has been entered into the record and has been fully considered. Claims 1-12 are canceled. New claims 13-41 are pending.

3. Applicant confirmed the cancellation of claims 9-12 in a telephone interview with the examiner on 2-10-2000.

4. Newly submitted claims 13, 21-23, and 25-27, are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the invention is no longer drawn to peptides but to peptides conjugated to moieties of the species (a) a toxin, (b) a drug, (c) a chemotherapeutic agent, (d) a cell and (e) a liposome.

5. The conjugates are distinct from the peptides per se because the conjugates possess different structural and functional characteristics which are not shared in common with the peptides of Groups I, i.e., for example the peptides do not provide for the delivery of a toxin, a drug, a chemotherapeutic agent, a cell or a liposome to the brain. The conjugates are classified for example in class 424, subclass 1.11 (radionuclinde containing peptides) and class 424, subclass 450 (liposomes). The distinct compounds possess different functional characteristics, for example capable of visualization by irradiation and the ability of killing a cell by delivery of a toxin and are made by different methods.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and recognized divergent subject matter restriction for examination purposes as indicated is proper.

7. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 13, 21-23 and 25-27 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

8. This application contains claims 13, 21-23 and 25-27 are drawn to an invention nonelected with traverse in Paper No. 8, received 11-29-99. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

9. As a result of applicants amendment, all rejections not reiterated herein have been withdrawn by the examiner.

Rejections Maintained

Claim Rejections - 35 USC § 112

10. Claims 14-20, 24 and 28-41 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:3 does not reasonably provide enablement for selective brain homing of any other peptide sequence. The specification does not

enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants argue that demonstration of at least 2-fold greater specific binding is sufficient to establish that a peptide of the invention homes to brain without additional laboratory analysis. Further applicants argue that in spite of the lack of competition of CENWWGDVC SEQ ID NO:2 by CLSSRLDAC SEQ ID NO:3, CENWWGDVC SEQ ID NO:2 is a brain homing peptide and the lack of competition merely indicates that CENWWGDVC specifically homes to brain by binding a different target molecule than the molecule recognized by CLSSRLDAC SEQ ID NO:3.

These arguments have been considered but are not persuasive. It is noted that the assertion that a peptide has at least 2-fold greater specific binding is sufficient to establish that a peptide homes to brain are limitations not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Further, contrary to applicants assertion, the specification states that in order to confirm the specificity of a peptide for directing homing to a selected organ, peptide competition experiments were performed. In the example SEQ ID NO:3 inhibits its own incorporation to brain. Thus indicating a relative specificity in the peptide homing to brain since the same synthetic peptide inhibited the homing of phage expressing that sequence by about 60%. No other peptide demonstrates this specificity since none were tested. Although this test provides an indication

that a peptide may selectively home, the peptide is only measured with respect to a single organ other than brain (kidney). "Selective homing" indicates that the peptide is more abundant in that organ than any other control organ. As no other organs have been tested, the skilled artisan would have reason to doubt that the peptide selectively homed to brain in the absence of data showing that in following administration, the peptide selectively homed to brain over any other control organ. Thus, the scope of enablement is not commensurate with the scope of the claims, in particular with respect to the recited formulas of untested peptide sequences and sequences comprising certain SEQ ID residues, and one of skill in the art would be required to perform further experimentation to establish that the peptides selectively homed to any particular organ.

Status of Claims

11. No claims are allowed.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

13. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973.

Sharon L. Turner, Ph.D.
February 14, 2000

Patricia A. Duffy
PATRICIA A. DUFFY
PRIMARY EXAMINER